

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) <b>FXH1006USC1</b>									
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]  on _____  Signature _____  Typed or printed name _____	Application Number <b>10/625,145</b>	Filed <b>July 22, 2003</b>									
	First Named Inventor <b>Stephen W. Boyd</b>										
	Art Unit <b>3731</b>	Examiner <b>Vi X. Nguyen</b>									
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table style="width: 100%;"><tr><td style="width: 50%; vertical-align: top;"><input type="checkbox"/> applicant/inventor.</td><td style="width: 50%; text-align: center; vertical-align: top;">_____ /Terry L. Wiles/ Signature</td></tr><tr><td style="vertical-align: top;"><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td><td style="text-align: center; vertical-align: top;">_____ Terry L. Wiles Typed or printed name</td></tr><tr><td style="vertical-align: top;"><input checked="" type="checkbox"/> attorney or agent of record. Registration number <b>29,989</b></td><td style="text-align: center; vertical-align: top;">_____ 651-330-4780 Telephone number</td></tr><tr><td style="vertical-align: top;"><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td><td style="text-align: center; vertical-align: top;">_____ March 24, 2010 Date</td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<input type="checkbox"/> applicant/inventor.	_____ /Terry L. Wiles/ Signature	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	_____ Terry L. Wiles Typed or printed name	<input checked="" type="checkbox"/> attorney or agent of record. Registration number <b>29,989</b>	_____ 651-330-4780 Telephone number	<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	_____ March 24, 2010 Date
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<input type="checkbox"/> *Total of _____ forms are submitted.											

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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## **REMARKS**

In the Final Office Action dated November 24, 2009 the Examiner rejected claims 16, 28 to 30 and 33 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,263,236 to Kasinkas et al. (Kasinkas). Applicant requests a pre-appeal brief review of the final rejection of these claims based upon the following clear error:

(1) The Examiner's determination that Kasinkas discloses all of the limitations of claim 16 is erroneous since the Examiner applied an incorrect legal standard by combining elements disclosed by Kasinkas in different, alternative embodiments to support the rejection

Claims 16 and 28 are the only pending independent claims. Each is directed to a device for removing material from a vessel wall at a vascular site. The device includes a cage and a material removing element. The cage has a plurality of openings and an inner surface which defines a cavity. The cage is moveable from a collapsed position to an expanded position. The cage is configured such that when the cage is in the expanded position at the vascular site material from the vessel wall extends from the vessel wall into the openings. The cage is releasable so that the cage may be left within the patient. The material removing element is positioned within the cavity and is configured to be moveable along the inner surface of the cage to remove material from the vessel wall which extends through the openings. Claim 16 further recites that the plurality of openings are formed by rigidly connected elements.

In rejecting claim 16 the Examiner states that Kasinkas discloses a cage 18 which is moveable from a collapsed position to an expanded position, the cage having a plurality of openings in the expanded position, the openings being formed by rigidly connected elements 20b. The Examiner states that Kasinkas includes a material removing element 20c positioned within the cage to remove the material from the vessel wall extending into the cage when the cage is in the

expanded position. The Examiner further states that the material removing element is configured to be movable along the inner surface of the cage to remove the material extending into the openings and cites to Kasinkas, col. 6, lines 15 to 20 in support of that statement.

Applicant submits that if Kasinkas is reviewed under the correct legal standard Kasinkas does not disclose a device which anticipates claim 16. In Net MoneyIN, Inc. v. VeriSign, Inc., 545 F. 3d. 1359. 1371 (Fed. Cir. 2008) the Federal Circuit clarified that “unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.” As stated in more detail above, claim 16 is directed to a device which is comprised of a number of elements including (1) a cage having a plurality of openings formed by (2) rigidly connected elements, and (3) a material removing element positioned within the cage cavity. According to the Examiner Kasinkas discloses a cage 18 having a plurality of openings formed by rigidly connected elements 20b and a material removing element 20c positioned within the cage cavity.

The error in this rejection is that the Examiner has identified elements from different embodiments of Kasinkas as disclosing the invention of claim 16. In other words, the elements disclosed in Kasinkas which the Examiner identifies as disclosing the limitations of claim 16 are not arranged or combined by Kasinkas in the same way as recited in claim 16. Element 20b is one form of an expansion mechanism shown, for example, in the embodiments of FIGS. 7 and 8. The embodiments of FIGS. 7 and 8 have cage wires 32 that are expanded by retraction of a pull wire 34. (Kasinkas, col. 5, lines 5 to 9). Element 20c is an alternative shape memory expansion mechanism of a separate embodiment shown, for example, in FIGS. 9 and 10. (Kasinkas, col. 5, lines 16 to 29). As a matter of fact Kasinkas discloses numerous embodiments of an expandable energy delivering

catheter, each having an expansion mechanism comprising one of elements 20 (FIGS. 1, 2 and 6), 20A (FIG. 3), 20B (FIGS. 7 and 8), or 20C (FIGS. 9 and 10). These alternative expansion mechanisms function to expand to cause a distributor 18 to come into contact with the wall of a vessel lumen. (Kasinkas, col. 5, lines 43 to 50). No single embodiment disclosed by Kasinkas includes more than one expansion mechanism. More specifically, Elements 20b and 20c are not disclosed together as elements of a single embodiment. This is understandable since elements 20b and 20c are merely alternatives of the same element. Kasinkas does not disclose nor teach that elements 20b and 20c would be used together in the same embodiment. Since these elements provide the same function there would clearly be no reason to combine them in a single embodiment. Thus, Kasinkas does not disclose all of the limitations of claim 16 arranged or combined in the same way as recited in the claim. The rejection of claim 16 as being anticipated by Kasinkas is, therefore, improper because it is based on a combination of features of different embodiments of the same reference, contrary to the proper legal standard. Claims 63 and 64 depend from claim 16 and are allowable for at least the same reasons as claim 16.

#### Conclusion

The Examiner's rejection of claim 16 as being anticipated by Kasinkas is clearly erroneous for the reasons set forth above. Therefore, the rejection of claim 16 and claims 63 and 64 which depend therefrom should be withdrawn. Applicant respectfully requests pre-appeal brief review of the issue.